LUER-RECEIVING MEDICAL VALVE AND FLUID TRANSFER METHOD

**NOTICE: More than one application for Reissue of U.S. Patent No. 5,549,651 has been filed. This Reissue Application is a Continuation of Reissue Application No. 09/140,413 filed August 26, 1998, now ~~allowed and Issue Fee paid~~.

U.S. PATENT NO. RE 37357

BACKGROUND AND SUMMARY OF THE INVENTION

The risk of needlestick injury and the expense associated with accessory cannulae, whether blunt or sharp, are well known. Conventional intravenous tubing systems utilize tapering luer male cannula connectors, often within an associated surrounding threadable member defining a luer-lock connector commonly used for achieving tight, sustained connections. A bare luer taper cannula without the associated threadable member is commonly called a luer slip connector and is widely utilized for brief prn injections. Both of these luer systems are in wide use throughout conventional hospital systems and it would be preferable to develop a connecting valve system which receives and is activated by conventional luer slip tapers or luer lock tapers so that incorporation into existing hospital systems is rapid and associated with minimal cost. It would be advantageous for such systems to avoid deadspace so that the surface could be easily wiped with antiseptic to avoid the need for capping after each use. Furthermore, the elimination of deadspace allows for the aspiration of blood through such systems without the collection of blood within the deadspace. Another important feature of such systems is the minimization of "kickback"—that is, it is important that the luer slip tip or luer lock systems, when not tightly locked, do not kickback out of the valve, thereby producing the potential for a spurt of blood or fluid into the environment and potential contamination of the operator. The prior art includes several luer-receiving valves which do not have substantial deadspace. U.S. Pat. No. 5,201,725 discloses shows a valve which utilizes an elastomeric member which opens by force induced by a threadable member over the elastomeric septum piston. Such a system will not work with a conventional luer lock system since the male taper extends centrally adjacent the luer lock threading member and therefore, it would not be possible to compress the septum piston within the luer-lock threads in such a system without inserting the male member itself into the septum piston. The background discussed in the aforementioned patent provides additional background for the present invention.

A device, designated the CLAVE™, for an injection port marketed by McCaw, is included in the Prior Art. This device utilizes a cannula surrounded by a septum piston. The septum piston is compressed by the luer taper, thereby allowing the needle and its associated bore to enter the bore of the luer taper, thereby opening fluid communication. However, such systems would be expected to be associated with substantial kickback when used with a luer slip system since the septum piston must be relatively resilient to prevent leakage associated with higher fluid pressures within the cannula. Further, the requirement of a spike or cannula within the bore of the valve results in considerable increase in expense associated with complex insert molding of the device. It is, therefore, preferable to develop a more simplified valve system which can receive a luer taper cannula and which eliminates the need for complex insert molding to minimize the potential for kickback and the potential for trapped fluid or blood while still providing a deadspace-free surface which can be easily wiped with antiseptic.

In general, the present invention comprises a housing including a main conduit having a main bore and further having a branch extending away from the main conduit and

including a secondary bore extending through the branch in fluid communication with the main conduit. The secondary bore may be aligned directly with the main conduit or may branch from the main conduit. The main conduit may, for example, comprise a catheter or may be a primary intravenous tubing system or arterial line. The secondary bore defines a longitudinal axis. An elastomeric septum piston is disposed within the secondary bore and at least a portion of the elastomeric septum piston is moveable by either compression or by longitudinal advancement along the secondary bore toward the main bore. In one preferred embodiment, the septum piston is cylindrical and includes a centrally positioned slit extending along the longitudinal axis of the cylindrical septum piston. The cylinder includes a proximal end and a distal end. The proximal end preferably extends to a position adjacent the proximal end of the secondary bore so that the surface of the proximal end of the septum piston is easily accessible adjacent the proximal end of the branch and therefore can be easily wiped with antiseptic. This is an important feature since it eliminates the need for capping after blood aspiration or drug injection. The bore of the secondary branch preferably includes two opposing projecting members along a distal portion of the bore which effectively narrow the diameter of the bore along at least a portion of one longitudinal axis. In the preferred embodiment, the central slit through the septum piston defines a longitudinal axis transverse to the longitudinal axis of the septum piston. With this embodiment, the longitudinal plane of the narrowed distal portion of the secondary bore is aligned with the longitudinal axis of the slit through the elastomeric septum piston. Furthermore, the elastomeric septum piston is sized to be transversely compressed by the projecting distal portions of the secondary bore. Since the slit is aligned with the projecting portions, transverse compression of the septum piston occurs along an axis which corresponds with the longitudinal axis of the slit so that when the elastomeric member is pushed from a proximal position into a distal position, the elastomeric member is transversely compressed by the projecting portions along the distal secondary bore, the compression causing the formerly tightly-closed slit to shorten and thereby open, allowing fluid to pass through a nascent flow channel formed by the shortened slit through the elastomeric septum piston. When the septum piston retracts away from the distal portion back into the proximal portion, the slit returns to its tightly closed position, thereby occluding further fluid communication through the septum piston.

In the preferred embodiment, the projecting portions progressively lengthen to define a progressively decreasing distance between the projecting members so that the projecting members are closer to one another adjacent the main bore than adjacent the proximal cylindrical portion of the secondary bore. This effectuates a progressive enlargement of the opening through slit of the elastomeric septum piston when the elastomeric septum piston is fully advanced into the proximal portion of the secondary bore. Furthermore, after removal of the luer, as the elastomeric septum piston retracts away from the distal compressing portion toward the proximal portion, the slit progressively closes from its proximal extent toward its distal extent, thereby expressing fluid toward the main bore rather than toward the proximal opening of the secondary bore. This reduces the chance of blood or fluid refluxing out of the septum piston into the environment or into the secondary bore when luer taper cannula is withdrawn from the secondary bore. The branch of the main conduit can be aligned directly with or perpendicular to the main conduit or can be at an oblique or acute

angle with the main conduit. The main conduit is generally discussed below as integral with the valve, but the main conduit may be a separate piece and sold separately, and may be joined with the branch or the aligned secondary bore by a threadable member as ,for example, joining a conventional heparin well or prn adapter to a catheter, stopcock, or IV tubing system. The branch preferably includes at least one external thread or thread receiver for receiving an internal female threading member to allow a secure threaded connection with a conventional luer-lock type connector of the type commonly used with conventional syringes or intravenous tubing systems. The use of this luer-activated valve in association with IV piggyback administration generally would require the recapping of the luer taper after use so that the luer taper remains sterile between IV piggyback mediation administrations. My U.S. Pat. No. 5,167,643 (the disclosure of which is hereby incorporated by reference as if completely disclosed herein) describes a Docking Station for receiving a blunt cannula such as a tapered luer end to maintain the sterility of the tapered end. The present invention includes the secondary tubing system having a docking station intended for use with a conventional luer taper cannula of the slip tip or luer lock type. This station utilizes a simple membranous cover since the primary function of the cover is to cover and seal the luer within the station, as discussed in the previous patent. The new protection station may include an annular shield for protecting the fingertips against inadvertent contact of the luer taper since the luer taper has been removed from fluid connection with the patient's blood vessel and, therefore, could be contaminated by potentially infectious material which, by even surface contamination of a nurses fingers, could subsequently enter a fissure in the fingers or otherwise be transferred to a mucous membrane where infection could ensue. The station preferably includes a connecting portion for connecting to a proximal portion of the intravenous piggyback system or supporting pole, as described in my aforementioned patent. The combination of a primary fluid system which incorporates a luer-activated valve and a secondary system which incorporates a luer cannula protection station which protects the tapered blunt cannula of the luer provides reliable intermittent connection to the patient with assurance that the luer taper remains sterile between use and eliminates the need for the utilization of multiple caps, thereby reducing overall cost.

It is the purpose of the present invention to provide an inexpensive medical valve which can be activated by a conventional luer taper cannula and thereby be widely implemented within existing hospital systems.

It is further the purpose of this invention to provide a medical valve which can be easily wiped with antiseptic to eliminate the need for recapping after use. It is further the purpose of this invention to provide a medical valve having substantially no deadspace adjacent its proximal portion to eliminate the pooling of blood or liquid within the valve so that the valve may be repetitively used for the aspiration of blood and reinjection of liquids. It is further the purpose of this invention to provide a luer-activated opening of a central fluid path which is automatically aligned with the bore of the luer and which will directly communicate with the bore of a luer taper cannula upon the transmission of longitudinal force of the luer taper cannula against the septum piston, thereby providing a mechanism for the opening of a centrally-positioned fluid path at the same time tight sealing occurs adjacent the distal end of the luer taper cannula against the septum piston. It is further the purpose of this invention to provide a valve which progressively closes

from its proximal extent to its distal extent, thereby expressing residual fluid from the valve away from the environment. It is further the purpose of this invention to provide a two-piece valve which can be simply manufactured by the insertion of an elastomeric septum piston into a rigid tubular structure, thereby avoiding the need for expensive and complex insert molding.

These and other features will become evident from the summary and detailed description described below. Furthermore, these and other objects and advantages of the invention will be further set forth in the description which follows and, in part, will be learned from the description or may be learned by practice of the invention. The objects and advantages of the invention may be realized by means of the instrumentalities and combinations particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial perspective view of a longitudinal section of the luer-receiving valve with the piston septum being in its resting detented position.

FIG. **2** is a partial perspective view of a longitudinal section of the luer-receiving valve with the blunt luer taper cannula of the conventional slip-tip type fully inserted into the cylinder.

FIG. **3** is a perspective view of a section through lines **3.3** of FIG. **1**.

FIG. **4** is a top view of the septum piston in its resting state.

FIG. **5** is a top view of the septum piston in its fully advanced compressed state, showing the open slit.

FIG. **6** is a side view of the septum piston.

FIG. **7** is a side view of a septum piston having an additional distal portion for occluding the main channel and including a proximal elastic umbrella.

FIG. **8** is a side view of a septum piston showing the distal portion for occluding the main channel.

FIG. **9** is another embodiment showing the proximal soft and compressible deadspace filler in association with the septum piston.

FIG. **10** is a perspective view of a luer tapered cannula protection station.

FIG. **11** is a longitudinal section view of a luer tapered cannula protection station showing an adjacent conventional luer lock connector.

DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The luer tapered cannula receiving valve **5** (FIG. **1**) includes a main conduit housing **10** having a main bore **14** and a secondary branch or cylinder **18** having a secondary bore **22**. The cylinder **18** includes a distal end **26** adjacent the main bore **10** and a proximal end **30**. The cylinder **18** further includes a cylindrical proximal bore portion **34** sized to sealingly receive a conventional tapered luer male cannula **35** (as shown in FIG. **2**) and distal bore portion **38**. The proximal bore portion **34** is defined by inner cylindrical walls **42** and outer walls **43** and includes outer thread receiving post **44** adjacent the proximal end **30** (although complete outer threads may be provided). A distal bore portion **38** is defined by distal wall **46** having opposing projecting members **50** which effectively narrow the transverse width of the distal bore portion **38** along a longitudinal

plane through the opposing projecting members **50** (as best shown in FIG. **3**). A cylindrical elastomeric septum piston **60** having a distal end **61** and a proximal end **62** is provided and includes a centrally positioned slit **72** extending from the proximal end **62** to the distal end **61** which can, if desired, receive a steel blunt cannula or sharp needle (not shown). The elastomeric septum piston **60** can be comprised, for example, of silicone rubber or of latex rubber and is both resilient and compressible. The septum piston **60** is preferably sized to be tightly received within the cylindrical proximal bore portion **34** so as to effectively sealingly wipe the cylindrical side walls **42** of the proximal bore portion **34** upon movement of the proximal end **62** of the septum piston **60** back toward the proximal end **30** of the cylinder **22**, as will be discussed.

In the preferred embodiment, a silicone lubricant is provided to enhance the sliding piston-like action of the sealingly received septum piston **60** against the side walls **42** and **46** of the cylinder **18**. As noted previously, the slit **72** extends completely through the cylindrical septum piston **60**. The long transverse axis of the slit **72** (in the transverse plane of the septum piston) is aligned within the same plane as the longitudinal axis through the opposing projecting members **50** of the distal bore portion **38** (FIG. **1**). Furthermore, the transverse diameter of the distal bore portion along an axis perpendicular to the longitudinal plane of the projecting members **50** can be slightly greater than the transverse diameter of the septum piston **60** to thereby, during operation, receive a bulging portion of the septum piston **60**, as will be discussed.

A septum wiper **78** is provided and a bore detent **80** is provided to retain the elastomeric septum piston **60** within the secondary bore by receiving the septum wiper. The wiper **78** is flexible to provide a tight seal. A second wiper (not shown) can be provided adjacent the proximal end **62** to provide additional sealing. The wiper **78** includes a partial recess **79** for receiving the projecting members **50** to allow tight sealing when passing over the members **50**. After insertion, during manufacture, the septum detent wiper **78** engages the detent **80**. As shown, the septum wiper **78** is configured so as to allow distal displacement of the septum piston **60** out of its detented position (of FIG. **1**), but to prevent proximal bore displacement of the septum piston **60** out of its detented position.

In operation, when a connection, injection, or aspiration is required, a conventional luer taper cannula **35** having a central opening **94** is inserted into the proximal bore portion **34** of the cylinder **18**. Advancement of the luer taper cannula **35** causes longitudinal displacement of the septum piston **60** from within the proximal bore portion **34** into the distal bore portion **38** between the projecting portions **50**. This causes compression of the septum **60** in an axis which is aligned with the long transverse axis of the longitudinal slit **72** so that the slit **72** is transversely shortened, and thereby opened to define an open fluid flow channel **100**. The formerly cylindrical septum piston **60** is narrowed in one transverse axis and bulges and widens in the perpendicular transverse axis, thereby producing an ellipse with a shortened and now opened central slit **72** (FIG. **2** and FIG. **5**), although the actual configuration within the cylinder may be limited in situ by the cylinder wall **46**. As noted previously, the projecting members **50** progressively enlarge to progressively narrow the width of the distal portion **38** between the projecting members **50**. If the elastomer is soft, this will cause the slit **72** to progressively shorten from its proximal extent toward its distal extent and, therefore, the flow channel **100** will be narrower in the proximal extent and

wider toward the distal extent. If the elastomer is comprised of a harder elastomer such as high durometer silicone, for example, exceeding 60 durometer-A medical grade), then the slit **72** will be wedged widely open along its entire length.

After the injection or aspiration is complete, the luer taper cannula **35** is withdrawn from the proximal portion **34** of the cylinder **18**. Upon removal of the luer taper cannula **35**, the septum piston **60** rebounds gently from its formerly advanced position back into its proximal sealing position with the proximal end of the septum piston returning to a position adjacent the proximal end **30** of the cylinder **18**. The lubrication of the septum piston **60** and the progressive narrowing of the opposing members **50** causes the resilient septum piston **60** to rebound back from its advanced position. By using a slowly progressive taper, the force of the rebound can be minimized to prevent kickback of the luer **35** from the proximal portion **34** of the cylinder **18**. In addition, an umbrella, as will be discussed, could be attached so as to provide less redundancy and, therefore, to provide elastic rebound. As discussed previously, during the return of the septum piston **60** back toward its resting position, the flow channel **100** can progressively close from its proximal extent to its distal extent to effectively express any liquid contained within the flow channel **100** back toward the main bore **10**, rather than out toward the cylinder **18**.

It can be seen that, by utilizing the achievement of lateral compression by the application of longitudinal displacing force against the septum piston, the rebound force of the septum piston is minimized. In other words, despite the fact that the valve is engaged by longitudinal force of the luer taper, the valve is actually opened by lateral compressive force of the cylinder wall or projecting members, rather than the directly applied activating longitudinal force. Therefore, it is not necessary to have a high resisting longitudinal rebound force to achieve and maintain a tight seal. For this reason, it is not necessary for this valve to utilize a deadspace filler of the type described in my U.S. Pat. No. 5,178,607, as will be discussed later. However, the implementation of deadspace displacement or filler provides an opportunity for utilization in valve, septum piston, or piston configurations wherein deadspace is present and wherein it is desirous to eliminate this deadspace so that recapping is not necessary.

Another similar septum piston embodiment, as shown in FIG. 7, the septum piston **60'** can include an integral latex or silicone elastic membranous umbrella **64'** which can drape over the outer walls **43** and can be bonded or otherwise securely attached to the outer walls **43** along the umbrella end **65'** when the septum piston **60'** is inserted into the proximal bore portion **34**. This prevents any potential opening at proximal end **30** adjacent inner walls **42** and septum piston **60'**. A redundant or bulging umbrella portion **66'** may be provided and the umbrella attached distally to allow the redundant portion **66'** to be free and to allow less inhibition of longitudinal displacement of the integral septum piston **60'** into the distal bore portion **38** during operation.

In another septum piston embodiment (FIGS. **7** and **8**), a projecting main bore occluding member **102'** is provided adjacent the distal end of the septum piston **60'**. The occluding member **102'** includes a circular distal end **104'** and is sized to be sealingly received into the main bore **10** when the septum piston **60'** is advanced. For operation of this embodiment, the cylinder **18** is preferably positioned at an angle relative to the main housing **10** and the secondary bore **22** intersects the main bore **10** at an angle which may be 30°–900° (as in FIG. **1**). The main bore **10** is connected

distally to a distal conduit which is in fluid connection with a patient's blood vessel. The main bore **10** is connected proximally to a proximal conduit which is in fluid connection with a primary fluid source, such as a high pressure flush bag or a bag of intravenous fluid. The operation of this embodiment is similar to the aforementioned embodiment; however, the occluding member **102'** extends distally upon advancement of the septum piston **60'** so that the occluding member **102'** passes the flow deflector **110'** and occludes the main bore **10** adjacent the cylinder **18** in a position intermediate the cylinder **18** and the primary fluid source. This embodiment provides closure of fluid connection between the secondary bore **22** and the primary fluid source, as well as between the patient and the primary fluid source during either aspiration or injection of fluid from the secondary bore **22**. This embodiment, therefore, functions to open communication between the opening **94** of the luer **35** and the patient through the septum piston **60'** and the main bore **10**, while at the same time automatically occluding fluid communication between the primary fluid source and the patient, as well as occluding communication between the primary fluid source and the opening **94** of the luer cannula **35**. During injection, this automatically prevents reflux of fluid upstream toward the primary fluid source and assures that the injected fluid is injected toward the patient. During aspiration, this assures that aspiration will come from the patient and not from the primary fluid source. The flow deflector **110** can also be sized so that it is engaged by the distal end **61'** of the septum piston **60'** to prevent excessive advancement of septum piston **60'**, thereby also functioning as a septum piston stop.

In another embodiment (FIG. **9**), the septum piston **60"** is shorter and a soft deadspace filler **140"** is provided. The deadspace filler can be of the type and design for use with very blunt cannulae as discussed in my U.S. Pat. No. 5,178,607 (the disclosure of which is hereby incorporated by reference as if completely disclosed herein). The soft outer filler **140"** serves to minimize kickback of the luer taper cannula **35** and functions as a deadspace occluder or displacer. The soft filler **140"** can be comprised of foam rubber which can be covered by a medical grade silicone of the type similar to that used in foam cuffs sold by the Bavona Corporation for tracheostomy tubes or can be otherwise constructed to have a similar ease compressibility and relatively low volume in the compressed state and high volume in the resting non-compressed state. The soft portion **140"** provides a central perforation **152"** for receiving the luer taper cannula **35** through the portion **140"** and subsequently into contact with the less easily compressible septum piston **60"**. Although it is preferred that the two portions be bonded together, they may be separate and the proximal portion may be bonded to the proximal inner walls **42** or the cylinder end **30** or may include an umbrella of the type shown in FIG. **7** or may include another attaching member. As can be seen, the outer soft, easily displaceable filler **140"** functions as a deadspace displacer to allow receipt of an extremely blunt cannula, such as a luer taper cannula **35**, into a fixed position in relationship with a more stiff and less compressible valve or septum piston **60"**, the septum piston **60"** functions as the actual valve to provide a tight seal and to prevent leakage of even high pressure fluid within the main bore **10**. It is the combination of a soft, easily compressible and displaceable outer member **140** in association with a tight sealing lower septum piston or valve **60"** which achieves the ability to splint a luer taper cannula **35** in position for reliable engagement with the actual valve mechanism **60"**, while at the same time allowing for the

elimination of deadspace by the soft, easily compressible outer member **140**".

It should be clear that alternative configurations of the septum piston are possible within the scope of the present invention. For example, at least a portion of the septum piston may be elliptical in cross-section, with the long transverse axis of the slit aligned with the long axis of the ellipse, and with the projecting septum piston compressing members being aligned with the long axis of the ellipse. This configuration could result in enhanced opening of the slit. The septum piston could be otherwise distorted, either longitudinally or horizontally, in association with longitudinal displacement to achieve an open fluid path. It is, however, preferable that this open fluid path extend through the septum piston and directly in contact with the bore of the luer taper cannula so as to facilitate flow and to absolutely minimize the trapping of fluid or blood within the valve.

FIG. **10** shows a luer taper protecting station **190**, which is intended to protect the blunt tapered luer cannula **192** connected to a secondary IV piggyback tubing system **194**. The station **190** includes a housing **200** having an open distal end **210** and a closed end **220** defining a chamber **222** having a bore **223**. The closed end **220** preferably includes a handle rod **224** and connecting or shield portion **226** for connection to an IV piggyback tubing or the protection station **190** may be otherwise connected along the piggyback system or the pole holding the piggyback system so as to allow easy storage, as discussed in my aforementioned patent. In the preferred embodiment, the open end **2 10** is occluded by an elastomeric boot **230** which has a closed longitudinal slit **235** . The boot is preferably of thin membranous elastomeric material, such as latex rubber or silicone and may be bonded to the housing **200** or otherwise secured. An opening **236** in boot **230** is preferably provided to receive the thread receiving post **244** which is tall enough to threadably engage with the female threading member which is carried by a conventional luer lock connector without disruption of the boot **230**. If necessary to prevent the threads of the luer lock from potentially disrupting the boot during threading, two tall posts may be provided on opposite sides of the housing **200**. The boot **230**, when attached to the distal end of the station **190**, produces a distal face **250** which is easily swabbable with antiseptic. As noted, the boot **230** material is preferably membranous elastic and resilient so that, despite the fact that the male luer taper **192** is close in diameter to the internal transverse dimension of the bore of the station, the elastic boot can be deflected laterally against the inner walls **254** of the station **190** so that even the large diameter of a luer taper **192** can be received within the bore **223** of the station **190** without being inhibited by the low displacement volume and, indeed, easily displaceable elastic boot **230**. This is an important feature since there is relatively little clearance between the outer surface **256** of a conventional male tapered luer cannula **192** and the inner surface **260** of the threadable luer lock connector **270** surrounding the taper **192** which must be received over the station **190**. It is, therefore, important that the sealing member has a very low displacement or compressed volume so that luer lock connector **270** may be fully received over and through the boot **230** and into the station **190** without the advancement of the cannula **192** fully into the bore **222** being inhibited by the displaced face **250** of boot **230**.

Although an elastic membranous boot is shown, a perforated deadspace filler, of the type previously discussed with a compressed low displacement volume, may be used to fill the bore of the station and to receive and cover the luer taper.

It is considered advantageous, as with the present invention, to provide a central perforation and flow channel which